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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
KEI KIRIBAYASHI, ET AL. : EXAMINER: HENRY, M.C.
SERIAL NO: 10/533,538 :
FILED: MAY 2, 2005 : GROUP ART UNIT: 1623
FOR: PERITONEAL DIALYSIS :
METHOD :

REPLY BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

In response to the Examiner's Answer ("EA") dated February 17, 2011,
the Appellants respectfully traverse the Examiner's positions.

A. The Examiner substantially reiterates the final rejection on pages 3-11
of the Examiner's Answer and argues on lines 9-12 on page 11 of the EA that (i):

the Examiner has not misinterpreted the disclosure of Isono, et al.
because Isono, et al. disclose a peritoneal dialysate composition
comprising 1 to 8 g/dL. . .and electrolytes; wherein said
composition can be used as a peritoneal dialysate (*see col. 2, lines
5-46*). (emphasis added)

This statement alone shows that the Examiner has already misconstrued
the disclosure of Isono, et al. because only col. 2, *lines 5-21* describe a dialysis
solution. The Examiner's interpretation of col. 2, *lines 22-46* (reproduced below)
as disclosing a dialysis solution is simply wrong as apparent from this section of
Isono which is directed, not to dialysis solutions, but to organ-preserving
solutions:

As organ-preserving solutions, Eurocollin's solution, Wisconsin's solution and the like have been proposed. The followings can be mentioned as illustrative components for the preparation of Eurocollin's solution:

	K ₂ HPO ₄	7.40 g/l
	NaHCO ₃	0.84 g/l
	KH ₂ PO ₄	2.04 g/l
30	KCl	1.12 g/l
	MgSO ₄	0.48 g/l
	Heparin	5,000 units/l
	Osmotic pressure	326 mOsm/kg

It has also been proposed to have organ-preserving solutions added beforehand with antibiotics, physiologically-active proteins (insulin, antiplatelet factors, antidiuretic hormones, and the like), saccharides (glucose, mannitol, and the like), vitamins (vitamin C, vitamin E, and the like), organic acids (lactic acid, citric acid, and the like), nucleic acid bases (adenosine triphosphate, and the like), antihypertensives (calcium antagonists, β -adrenocaptive antagonists, angiotensin converting enzyme inhibitors, and the like), anticoagulants (heparin, and the like). Further, addition of drugs such as the phosphoric diester compounds disclosed in Japanese Patent Laid-Open No. 215801/1995 has also been proposed.

While col. 2, lines 5-21, does disclose a peritoneal dialysate there is no disclosure of any peritoneal dialysate that *contains ATP*, see section reproduced below:

- 5 On the other hand, a peritoneal dialysate has, for example,
the following composition and properties.
Electrolyte concentrations (mEq/l):

10	Na ⁺	130 to 150
	K ⁺	as needed
	Ca ²⁺	1 to 6
	Mg ²⁺	0 to 3
	Cl ⁻	90 to 135
	CH ₃ CH(OH)COO ⁻	30 to 45
	Glucose (g/dl)	1 to 8
15	Osmotic pressure (mOsm/l)	300–680
	pH	about 5.5

- 20 An acetate or lactate yields bicarbonate ions in vivo, and
serves to replenish bicarbonate ions which are consumed
during dialysis.

On page 11, lines 12-14 of the EA, the Examiner again mischaracterizes the disclosure of Isono stating “Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution *can be added to said peritoneal dialysate* (see col. 2, lines 5-46, *especially lines 34-46*)” (emphasis added)¹. However, there is no such teaching in Isono to add ATP to a peritoneal dialysate.

The Examiner’s reference to lines 34-46 appears to misinterpret the phrase “have organ-preserving solutions *added beforehand* with antibiotics [etc.]” appearing on lines 34-35. This language has been apparently interpreted as meaning that an organ-preservation solution (ATP is deemed to be an organ-preserving solution) is added “beforehand” to a peritoneal dialysis solution during its preparation. However, this portion of Isono clearly describes addition of

¹ This same section of Isono is referenced again and again in the Examiner’s arguments on pages 11-24 of the EA. It is important to properly interpret this section as the Examiner’s arguments for obviousness depend on what it teaches.

substances like antibiotics, etc. that can optionally be added during the preparation of an organ-preserving solution, not a peritoneal dialysate. The Examiner has probably misinterpreted the term “added beforehand” meaning that ATP can be added to the peritoneal dialysates described in col. 2, lines 5-21. This is not a reasonable interpretation since the sentence beginning in col. 2, line 34 of Isono expressly refers to “organ-preserving solutions” making no mention at all to a peritoneal dialysis solution. Moreover, when read taking into account that the disclosure in Isono is based on an early Japanese publication, the term “added beforehand” means “supplemented”. This sentence clearly refers to supplementary additives to be “added beforehand” to an *organ-preserving solution*, not to additives to be added to an infusion or to a peritoneal dialysis solution. The Examiner’s interpretation of col. 2 of Isono as describing adding an organ-preserving solution (ATP) to a peritoneal dialysis solution is not correct. There is no suggestion anywhere in Isono to mix different types of solutions—infusions, peritoneal dialysates, or organ-preserving solutions together, and no suggestion at all to add adenosine triphosphate (ATP) to a peritoneal dialysate.

B. On page 3 of the EA, the Examiner merely reiterates the statement on page 2 of the final rejection (OA, dated April 2, 2010) and has not responded to the Appellants’ arguments in the Appeal Brief. These arguments, including that conventional peritoneal dialysis solutions that did not contain adenosine triphosphate (ATP) were well known in the art, remain uncontroverted. The Examiner has not explained why one of ordinary skill in the art reading claim 34 in light of the prior art, the specification, and the prosecution history would have not understood that this claim refers to a conventional dialysis solution supplemented with ATP.

RELIEF REQUESTED

For the reasons given in the Appeal Brief and for those above, the
Appellants maintain that all rejections should be REVERSED.


Respectfully submitted,

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